5164. Nutrilite food supplement. (F. D. C. No. 39346. S. No. 38–006 M.)

INFORMATION FILED: 10–12–56, N. Dist. Ohio, against Harold J. Kennedy, Youngstown, Ohio.

ALLEGED VIOLATION: On or about 1–26–56, the defendant, in the course of a sales talk to individuals, made oral representations that the article was an effective treatment for the diseases, symptoms, and conditions set forth below, which act resulted in the article being misbranded while held for sale after shipment in interstate commerce.

LABEL IN PART: (Pkg.) "Nutrilite (R) XX Food Supplement This package contains multiple vitamin capsules and mineral tablets for use as a dietary food supplement to fortify, or supplement, the diet."

CHARGE: 502 (f) (1)—the labeling of the article failed to bear adequate directions for use in the treatment of the diseases, symptoms, and conditions for which the article was intended, namely, cerebral thrombosis, blood clots of the heart and brain, arthritis, arteriosclerosis, high blood pressure, hay fever, asthma, diabetes, headaches, emesis, ulcerated stomach, general run-down condition, cataracts, and cancer.

PLEA: Guilty.

DISPOSITION: 11–30–56. Defendant placed on probation for 6 months.

5165. Aserpon tablets. (F. D. C. No. 38946. S. No. 23–628 M.)

QUANTITY: 10 100-tablet labeled btls. and 15,000 unlabeled tablets at Boston, Mass., in possession of R. J. Moran Co.

SHIPPED: On 4–6–55, a concentrate of reserpine was shipped from Brooklyn, N. Y., by Chas. Pfizer & Co., Inc.

LABEL IN PART: (Btl.) "Aserpon 0.25 mg. Caution: Federal law prohibits dispensing without prescription * * * Each tablet contains Reserpine 0.25 mg."

RESULTS OF INVESTIGATION: Upon receipt of the reserpine concentrate by the consignee at Boston, Mass., the concentrate was processed into tablets.

The tablets made from the concentrate were regarded as a new drug. However, the label of the concentrate when shipped did not bear the statement provided by the regulations for bulk material intended for use in the manufacture of a new drug; and the labeling of the article did not bear adequate directions for use, nor was the concentrate exempt from bearing adequate directions for use.

LIBELED: 2–13–56, Dist. Mass.

CHARGE: 502 (f) (1)—the labeling of the article, when shipped, failed to bear adequate directions for use.

DISPOSITION: 6–4–56. Default—destruction.

5166. Myo-Flex device. (F. D. C. No. 38647. S. No. 10–820 M.)

QUANTITY: 2 devices at Dickinson, Tex.

SHIPPED: In March 1954 and July 1955, by Mr. E. B. Dodd, from Shreveport, La.

LABEL IN PART: (Device) "The Edwards Neurotheraphy Modality 'Myo-Flex'."

ACCOMPANYING LABELING: Booklet entitled "1955 Edition of the Basic Procedure for Operating The Automatic Neurotheraphy Modality: 'The Edwards Myo-Flex'."

RESULTS OF INVESTIGATION: The device consisted of a cabinet housing various switches, transformers, condensers, vacuum tubes, and other electrical parts. When connected to the ordinary household electric supply, the device provided various types of electrical current output capable of causing stimulation of human muscles.

LIBELED: 11–10–55, S. Dist. Tex.; libel amended 3–2–56.

CHARGE: 502 (a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the article provided an adequate and effective treatment for abdominal adhesions, acroparesthesia, amenorrhea, partially ankylosed joints, arthritis, and partial ankylosis, asthma, atrophy (muscular), backache, bronchitis, contusions, subdeltoid bursitis (chronic), cerebral palsy, chilblains, constipation, deafness (chronic), depression, involutional depression, Dupuytren's contraction, dysmenorrhea, endocrine stimulation, epilepsy, eye conditions, headache, head colds, hemorrhoids, lumbago, menopause (hot flushes), medullar subshock, muscle spasm, menstrual pains, multiple sclerosis, muscle training, neuralgia, neurotic tension, paralysis, peripheral facial palsy (Bell's palsy), paralysis agitans, posterolateral sclerosis, prostatic hypertrophy, ptosis of the abdomen, Raynaud's disease, relaxed vaginal walls, rheumatism (chronic), sciatica, sinus conditions, hay fever, stomach conditions, Buerger's disease, trigeminal neuralgia, prolapse of uterus, visceroptosis, and wry neck; and 502 (f) (1)—the labeling of the article failed to bear adequate directions for use by laymen, and the device was not entitled to any exemption from the requirement of adequate directions for use since it was a prescription device and was not in the possession of a person legally entitled to employ it for medical purposes.

DISPOSITION: 7–24–56. Consent—claimed by Mr. E. B. Dodd, Dickinson, Tex.; relabeled and delivered to a licensed practitioner.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

5167. Pan-Vita syrup. (F. D. C. No. 38617. S. No. 9–596 M.)

INFORMATION FILED: 7–31–56, N. Dist. Calif., against Barnes-Hind Laboratories, Inc., San Francisco and Sunnyvale, Calif.

ALLEGED VIOLATION: On 11–11–49, the defendant gave to a firm engaged in the business of shipping drugs in interstate commerce a guaranty to the effect that all drug products shipped by the defendant to the holder of the guaranty would be neither adulterated nor misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act.

On 10–13–55, the defendant shipped a number of bottles of adulterated and misbranded *Pan-Vita syrup* to the holder of the guaranty at Los Angeles, California.

CHARGE: 501 (c)—the strength of the article differed from, and the quality of the article fell below, that which it purported and was represented to possess; and 502 (a)—the label statement "Each two teaspoonfuls (10 cc) contain: Vitamin A Palmitate . . . 5000 USP. Units Vitamin D (irradiated ergosterol). . . 500 USP. Units" was false and misleading since the article contained less vitamin A and vitamin D than declared.

PLEA: Nolo contendere.

DISPOSITION: 8–10–56. Fine, $500.